

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

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|                               | ) |                  |
| IN RE: AREDIA AND ZOMETA      | ) |                  |
| PRODUCTS LIABILITY LITIGATION | ) | NO. 3:06-MD-1760 |
|                               | ) | JUDGE CAMPBELL   |
| This Document Relates to Case | ) |                  |
| No. 3:08-0068 (Fussman)       | ) |                  |

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2289). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part as follows.

FACTS

Plaintiffs Rita and Herbert Fussman allege that Defendant's products Aredia and Zometa caused Mrs. Fussman to develop osteonecrosis of the jaw ("ONJ"). They allege five causes of action under North Carolina law: (1) negligent design, (2) negligent failure to warn, (3) breach of express warranty, (4) breach of implied warranty and (5) loss of consortium. Defendant has moved for summary judgment on all of Plaintiffs' claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*,

509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268. Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Id.*

### CAUSATION

Causation is a required element of all of Plaintiffs' claims. *Gaines v. Cumberland County Hospital System, Inc.*, 672 S.E.2d 713 (N.C. Ct. App. 2009) and N.C. Gen. Stat. § 99B-6 (negligence); *Driggers v. Sofamor, S.N.C.*, 44 F.Supp.2d 760 (M.D. N.C. 1998) (products liability); *Edwards v. ATRO SpA*, 891 F.Supp. 1074 (E.D. N.C. 1995) and N.C. Gen. Stat. § 99B-5 (failure to warn). Where the exact nature and probable genesis of a particular type of injury involves complicated medical questions far removed from the ordinary experience and knowledge of laymen, only an expert can give competent opinion evidence as to the cause of the injury. *Driggers*, 44 F.Supp.2d at 765.

Defendant first argues, for the reasons stated in its Motion for Summary Judgment Based on Failure of General Causation Proof under *Daubert*, that Plaintiffs cannot establish general causation. General causation is established by demonstrating that exposure to a substance can cause a particular disease. *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F.Supp.2d 465, 471 (M.D. N.C. 2006). The Court has found genuine issues of material fact as to general causation and denied Defendant's Motion related thereto.

Specific causation is established by demonstrating that a given exposure is the cause of a particular individual's disease. *Doe*, 440 F.Supp.2d at 471. Defendant asserts that Plaintiffs have no admissible expert proof as to specific causation in this case. The Court has not considered the testimony of Plaintiffs' non-retained, treating physicians with regard to specific causation for purposes of this motion. Defendant has moved to exclude Plaintiffs' other specific causation expert, Dr. Najjar, but the Court has denied that motion.

Under North Carolina law, the proximate cause of an injury is a factual question, and there may be more than one proximate cause of an injury. *Ross v. Washington Mut. Bank*, 566 F.Supp.2d 468, 479 (E.D. N.C. 2008). If there are multiple possible causes for an injury, the plaintiff must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result. *Id.*

Dr. Najjar's expert report states that he is "convinced, with reasonable medical certainty that Mrs. Fussman suffers from bisphosphonate induced alteration in her maxillary alveolar ridge due to her treatment with Aredia and Zometa." Najjar Expert Report, Ex. 2 to Docket No. 2505. Dr. Najjar testified that Mrs. Fussman had bisphosphonate-induced ONJ. Najjar Deposition (Ex. 7 to Docket No. 2505, p. 1438.

The Court finds that Dr. Najjar's testimony creates a genuine issue of material fact as to the specific cause of Mrs. Fussman's injury. Defendant may use all its arguments to cross-examine and attempt to discredit Dr. Najjar's testimony, but, for purposes of summary judgment, the Court finds that testimony sufficient to preclude summary judgment on this issue.

## NEGLIGENCE

In North Carolina, the essential elements of a products liability action predicated upon negligence are: (1) evidence of a standard of care owed by the reasonably prudent person in similar circumstances; (2) breach of that standard of care; (3) injury caused directly or proximately by the breach; and (4) loss because of the injury. In addition, a plaintiff must present evidence the product was in a defective condition at the time it left the defendant's control. *Nicholson v. American Safety Utility Corp.*, 476 S.E.2d 672, 676 (N.C. Ct. App.1996).

Plaintiffs' negligence claims (negligent design and negligent failure to warn) are both based upon the alleged failure to warn. Defendant first contends that its warnings were adequate. For the reasons stated in the Court's Memorandum denying Defendant's Motion for Summary Judgment on the Adequacy of the Aredia and Zometa Warnings, there are genuine issues of material fact as to the adequacy of Defendant's warnings, and summary judgment on this issue is, therefore, inappropriate.

Defendant also argues that Plaintiffs cannot show that any inadequacy of warnings was a proximate cause of Mrs. Fussman's injury. To hold a defendant responsible for a plaintiff's injuries, defendant's negligence must have been a substantial factor in causing the particular injuries for which plaintiff seeks recovery. *Gaines*, 672 S.E.2d at 716.

Defendant argues that Plaintiffs have not shown that a difference in warnings would have made any difference in the behavior of Mrs. Fussman and her physicians or prevented Mrs. Fussman's ONJ. Mrs. Fussman testified, however, that knowing what she does now about Aredia and Zometa and her jaw problems, she would not have taken either of those drugs. R. Fussman Deposition (Ex. 2 to Docket No. 2615), p.227. Dr. Shroer testified that had he known about bisphosphonates and ONJ at the time he treated Mrs. Fussman, his treatment course for her would

have definitely been different. Shroer Deposition (Ex. 8 to Docket No. 2615), p. 112. In addition, Dr. Wagoner testified that his treatment of and advice for Mrs. Fussman would have been different if he had his current knowledge of bisphosphonates and osteonecrosis of the jaw. Wagoner Deposition (Ex. 4 to Docket No.2615), p. 97.

The Court finds that Plaintiffs have offered sufficient proof to show that there are genuine issues of material fact as to whether the alleged failure to warn was a proximate cause of Mrs. Fussman's injuries.

### EXPRESS WARRANTY

In order to overcome a motion for summary judgment on a breach of express warranty claim, under North Carolina law, the plaintiff must present evidence tending to prove that the defendant made (1) an express warranty as to a fact or promise relating to the goods, (2) which was relied upon by the plaintiff in making his decision to purchase, and (3) that this express warranty was breached by the defendant. *Hall v. T. L. Kemp Jewelry, Inc.*, 322 S.E.2d 7, 10 (N.C. Ct. App. 1984). An express warranty arises if a statement of the manufacturer induces the purchase of the product. An express warranty is created when a seller makes any affirmation of fact or promise which relates to the goods and becomes part of the basis of the bargain. *Bryant v. Adams*, 448 S.E.2d 832, 842 (N.C. Ct. App. 1994) (citing N.C. Gen. Stat. § 25-2-313).

The only statements which Plaintiffs allege to be express warranties by Defendant are (1) an alleged statement from a doctor to Mrs. Fussman, (2) Mr. Fussman's discovery of information or the lack thereof on Novartis' website, and (3) a hearsay statement concerning an alleged statement from a Novartis agent. The Court finds that these statements are not "express warranties" under North Carolina law.

In any event, Plaintiffs have presented no proof that either they or their physicians relied upon any such statements in purchasing Aredia or Zometa. For these reasons, Defendant's Motion for Summary Judgment is granted as to the Plaintiffs' breach of express warranty claim, and that claim is dismissed.

#### IMPLIED WARRANTY

To recover for breach of implied warranty, a plaintiff must establish: (1) a merchant sold goods; (2) the goods were not "merchantable" at the time of the sale; (3) the plaintiff was injured by such goods; (4) the defect or other condition amounting to a breach of the implied warranty proximately caused the injury; and (5) the plaintiff so injured gave timely notice to the seller. *Bryant*, 448 S.E.2d at 467. Failure to warn of dangerous propensities concerning a product may create an action for breach of implied warranty. *Id.* at 468.

Thus, to avoid summary judgment on their breach of implied warranty claim, Plaintiffs have to show a genuine issue of material fact as to whether Defendant's warnings were inadequate and whether the alleged failure to warn proximately caused Mrs. Fussman's injuries. For the same reasons that they have carried that burden as to their negligent failure to warn claim, they have sufficiently carried it with regard to breach of implied warranty.


#### LOSS OF CONSORTIUM

As noted by both parties, Mr. Fussman's loss of consortium claim rises or falls with the claims of Mrs. Fussman. Accordingly, Defendant's Motion for Summary Judgment on this claim is denied.

## CONCLUSION

For these reasons, Defendant's Motion for Summary Judgment (Docket No. 2289) is GRANTED in part and DENIED in part. Plaintiffs' breach of express warranty claim is DISMISSED.

IT IS SO ORDERED.

  
TODD J. CAMPBELL  
UNITED STATES DISTRICT JUDGE